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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,856	03/07/2000	Olexander Hnojewyj	1849.16102-A CIP 2	8986

26308 7590 03/19/2003

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EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/520,856	HNOJEWYJ ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2002 and 21 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-108* is/are rejected.

7)☒ Claim(s) *109-119* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The Sequence Listing filed February 21, 2003 is approved.

2. The disclosure is objected to because of the following informalities: At page 5, line 11, a word, possibly "more", appears to be missing after "or". At page 9, line 34, the number "84" should be deleted from the end of the line. Appropriate correction is required.

3. Claims 13, 15, 16, 23, 25, 30, 84, 86, 87, 94, 96, and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 13, line 3, the language "group consisting essentially of" is unclear because it is not standard Markush language, and it is not clear whether the cross-linking group must be selected from the listed groups or not. It is suggested that "essentially" be deleted from the claim. The same language found in claims 15, 16, 23, 30, 84, 86, 87, 94, and 101 is also indefinite, as is the language "consisting essentially of comprising" in claims 25 and 96. Claims 25 and 96 are indefinite because chitosan and hyaluronic acid are not proteins. If claims 30 and 101 are going to be amended to use the standard Markush terminology "group consisting of", then the conjunctions used in the Markush groups need to be changed from "or" to "and". Claims 23 and 94 are indefinite because "serum" and "serum fractions" are not proteins.

4. Claims 2, 7, 9, 39, 41, and 82 are objected to because of the following informalities: The range recited in claim 2 has no upper limit because "greater than 500 days" has no upper limit. Accordingly, it would be simpler to recite that the desired degradation period is at least about 1 day. The language defining the ranges in claims 9, 39, and 41 should also be simplified. At claim 7, line 2, "Gly" and "collagenase" are misspelled. At claim 7, lines 2 and 3, the underlining marks should be changed back to hyphens. At claim 82, line 3, "Gly" and

"collagenase" are misspelled. A SEQ ID NO needs to be inserted after the tetrapeptide amino acid sequence recited in the claim. See 37 CFR 1.821(d). Appropriate correction is required.

5. Applicants are requested to check the dependency of claims 79, 81, 83-89, 91, 93, 95, 97-99, and 101-104. It is possible that these clams should depend upon claim 70 instead of claim 71.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-75 of U.S. Patent No. 6,458,147. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '147 patent anticipate instant claims 1-43. Because the protein solutions, polymer solutions, degradation control regions, and cross-linking groups are the same in the claimed invention of the '147 patent as in the instant claimed invention, inherently the claimed invention of the '147 patent will have the same degradation periods and cross-linking periods as are claimed in the instant claims. With respect to instant claims 44-108 , while the '147 patent does not claim its individual components in the form of a system including instructions for use, it would have been obvious to one of ordinary skill in the art to package the components of the

materials claimed in the '147 patent in the form of a system including instructions for use, because it is known and routine in the chemical and pharmaceutical arts to package reagents in the form of a system including instructions for use because this packaging form makes the storage, transportation, preparation, and use of the components easier for the artisan. With respect to the text per se of the instructions, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

8. Claims 1-5, 8-11, 17-23, 27-30, 33-80, 88-94, 98-101, and 104-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,371,975. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '975 patent anticipate instant claims 1-5, 8-11, 17, 18, 20-23, 27-30, and 33-43. Because the protein solutions, polymer solutions, degradation control regions, and cross-linking groups are the same in the claimed invention of the '975 patent as in the instant claimed invention, inherently the claimed invention of the '975 patent will have the same degradation periods and cross-linking periods as are claimed in the instant claims. With respect to claims 19 and 90, while the '975 patent claims a buffered protein solution, the '975 patent does not claim any particular buffer. It would have been obvious to one of ordinary skill in the art to use as the buffer in the claimed invention of the '975 patent a carbonate or phosphate buffer because these are known buffers capable of achieving the pHs claimed in the '975 patent and because the choice of any particular known buffer would not have been expected to affect materially the properties of the resultant material. With respect to instant claims 44-80, 88-94, 98-101, and 104-108, while the '975 patent does not

claim its individual components in the form of a system including instructions for use, it would have been obvious to one of ordinary skill in the art to package the components of the materials claimed in the '975 patent in the form of a system including instructions for use, because it is known and routine in the chemical and pharmaceutical arts to package reagents in the form of a system including instructions for use because this packaging form makes the storage, transportation, preparation, and use of the components easier for the artisan. With respect to the text per se of the instructions, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

9. Claims 1-3, 8-30, 33-38, 41-78, 83-101, and 104-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 09/780,014. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '014 application anticipate instant claims 1, 8-30, 33-38, and 41-43. Because the protein solutions, polymer solutions, degradation control regions, and cross-linking groups are the same in the claimed invention of the '014 application as in the instant claimed invention, inherently the claimed invention of the '014 application will have the same degradation periods and cross-linking periods as are claimed in the instant claims. With respect to instant claims 2, 3, 39, 40, 45, 48, 51, 54, 57, 60, 63, 66, 71, 74, and 77, while the '014 application claims the presence of a degradation control region in the first component, the '014 application does not claim the length of time over which degradation control is to occur. It would have been obvious to one of ordinary skill in the art in the claimed invention of the '014 application to choose a degradation

control region so that the time over which degradation is to occur is optimized, because the '014 application indicates in its claims that degradation control is a result-effective variable, and it is prima facie obvious to determine and optimize all result-effective variables. With respect to instant claims 44, 47, 50, 53, 56, 59, 62, 65, 68, 70, 73, and 76, while the '014 application does not claim the text of the instructions recited in each of these claims, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

11. Claims 8-11, 14, 16-19, 22, 26, 27, 30, and 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 97/22371. The WO Patent Application '371 teaches poly-L-lysine in a phosphate buffer combined with tetrafunctionally activated SE-PEG in PBS. The composition crosslinks and forms a gel almost immediately. See page 36, Example 4.

12. Claims 1-5, 8-11, 14, 16, 17, 20-27, 30, and 33-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Doi et al (U.S. Patent No. 4,839,345). Doi et al teach protein solutions crosslinked with polymer solutions wherein the crosslinking polymer can have a functionality of three or more, wherein from 1 to 3000 ethylene glycol units can be present in the polymer, and wherein a diacid links the crosslinking group to the ethylene glycol groups, and wherein the cross-linking group can be an ester of an N-hydroxysuccinimide. The protein can be, e.g., gelatin or albumin. The cross-linking groups react with amino groups contained in the protein to form a biocompatible adhesive gel. See, e.g., column 2, lines 36-43; Preparation Example 3; Example 3; and the claims. Gelatin is a water-soluble derivative of collagen. In view of the similarity in reactants, preparation method, and structure between the gel of Doi et al and Applicants' claimed biocompatible material, the gel of Doi et al is deemed inherently to have the same degradation periods and cross-linking periods as are claimed by Applicants. Sufficient

evidence of similarity is deemed to be present between the gels of Doi et al and Applicants' claimed biocompatible materials to shift the burden to Applicants to provide evidence that the claimed biocompatible materials are unobviously different than those of Doi et al.

13. Claims 44-80, 85, 87, 88, 91-98, 101, and 104-108 are rejected under 35 U.S.C. 103(a) as being obvious over Doi et al (U.S. Patent No. 4,839,345). Application of Doi et al is the same as in the above rejection of claims 1-5, 8-11, 14, 16, 17, 20-27, 30, and 33-43. Doi et al do not teach the reactants in kit form with instruction for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the reactants required by Doi et al in the form of a kit including instructions for use, because it is known and routine in the chemical and pharmaceutical arts to package reagents in the form of a kit including instructions for use because this packaging form makes the storage, transportation, preparation, and use of the components easier for the artisan. With respect to the text per se of the instructions, this does not impart patentability to compositions or articles of manufacture where the compositions or article of manufacture are otherwise anticipated by or obvious over the art.

14. Claims 28, 29, 99, and 100 are rejected under 35 U.S.C. 103(a) as being obvious over Doi et al (U.S. Patent No. 4,839,345) as applied against claims 44-80, 85, 87, 88, 91-98, 101, and 104-108 above, and further in view of Barrows et al (U.S. Patent No. 5,583,114). Doi et al teach the use of albumin in forming their biocompatible adhesive gels, but do not teach the use of human serum albumin in particular. Barrows et al teach forming adhesive sealants using human serum albumin because the HSA is safe, non-immunogenic, and readily isolated. See, e.g., column 3, lines 6-55. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the HSA of Barrows et al as the source of the albumin in

the adhesive gels of Doi et al because Barrows et al teach that HSA is a safe, non-immunogenic, and readily isolated source of albumin which can be used for the same purpose as in Doi et al. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal human serum albumin concentrations for the adhesive composition of Doi et al as modified above by Barrows et al because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the adhesive and pharmaceutical arts.

15. Claims 109-119 are allowed. The WO Patent Application 00/09087 is deemed the closest prior art of record to instant claims 109-119. However, the WO Patent Application "087 does not teach or suggest a material in which one of the macromers to be crosslinked is a protein.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
March 17, 2003